

WAGGONER

Appl. No. 09/740,486

May 17, 2004

REMARKS/ARGUMENTS

Reconsideration of this application and entry of this Amendment are solicited. At the very least entry of the Amendment is appropriate as it cancels claims that have been withdrawn from consideration and/or are directed to non-elected subject matter. In this amendment claims 9-12, 15, 19 and 21-24 are canceled responsive to the examiner's comments in items 2 and 3 of the Official Action leaving only claims 25-29 currently being examined in this application.

With regard to the Information Disclosure Statement and the Neblette reference noted in item 5 of Official Action, applicant is not at this point able to provide a copy of this reference.

Applicant is pleased to note the two previous rejections have now been withdrawn; *see* items 6 and 7 of the Official Action.

The essence of the present invention resides in the three prior art-based rejections set out in items 11, 12 and 13 of the Official Action. Two of the rejections (11 and 12) are set out in the alternative as being either based upon anticipation under 35 USC §102 or lacking patentability over the prior art under 35 USC §103(a). Applicant traverses all of these rejections.

Before discussing the anticipation components of these rejections it is useful to review the legal requirements to establish anticipation. To anticipate a claim, a single reference must disclose the claimed invention with sufficient clarity to prove its existence in the prior art. *Motorola Inc. v. Interdigital Technology Corp.*, 43 USPQ2d 1481, 1490 (Fed. Cir. 1997). Anticipation rejections are only proper when the "claimed subject matter is identically disclosed or described in 'the prior art,' without *any* need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference." *In re Arkley*, 172 USPQ 524, 526 (CCPA 1972); *see also Akzo N.V. v. International Trade Commission*, 1 USPQ 2d 1241, 1246 (Fed. Cir. 1986); *Ex parte Lee*, 31 USPQ 2d 1105, 1108 (BPAI 1993). Every element of the

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challenged claim must be disclosed within this single reference. *PPG Industries Inc. v. Guardian Industries Corp.*, 37 USPQ2d 1618, 1624 (Fed. Cir. 1996). Absence from the reference of any claimed element negates anticipation *Kloster Speedsteel AB v. Crucible Inc.* 23 USPQ 160 (Fed. Cir. 1986).

Neither of the anticipation rejections (11 and 12) of the current Action satisfies these requirements. Thus, applicant's claims are patentable over each of the cited references since they each fail to disclose each element of applicants' claims.

In the Official Action, item 11, it is alleged that all of the claims now being examined are either anticipated by or, in the alternative, obvious over either U.S. patent 4,404,289 or U.S. patent 4,406,711 (the Masuda et al patents '289 and '711). In a separate rejection directed towards claim 25-28 (and not claim 29) the examiner argues the same statutory category rejections, namely of anticipation or "obviousness" over an article by the inventor herein (and others) published in Biophysical Journal in 1981.

As stated previously (in the response of December 12, 2002), the Masuda references '289 and '711 disclose spectral sensitizers that are used to label trace components such as an antigen or an antibody. The reaction product is brought into contact with a silver halide sensitive photographic material, exposing to light and developing the exposed silver. The compounds used therefore possess the capability to impart spectral sensitization to silver halide.

Both of the Masuda patents relate to sensitizers that lack the feature that the cyanine, merocyanine, styryl and oxonol dyes are luminescent (and are therefore detectable by luminescence detection) as required by claims 25 and 26.

The Waggoner 1981 journal article discloses that the reactive sulphydryl group on the F1 region of cattle rhodopsin has been covalently labelled with a cyanine dye. The absorbance of the dye at 660 nm is sensitive to conformational changes of rhodopsin that occur following a short and intense light flash.

As with the Masuda references, this article is also silent on the fluorescence emission properties of the cyanine dye. Thus the 1981 Waggoner reference lacks the

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features of claims 25 and 26, i.e. that the cyanine dye must have a molar extinction coefficient of at least 50,000 liters per mole, have an average quantum yield of at least 5 percent and must absorb and emit in the 400 to 900 nm range when the photostable reaction product is in an aqueous environment.

The Heseltine patent relates to sulphonated cyanine and merocyanine dyes. They are useful as sensitizing dyes in photography (column 1, line 15). Heseltine lacks the feature that the dyes must contain at least one substituent to make the dye covalently reactive with a component as required by claims 25 and 26. Heseltine does not describe labelled components.

Claims 25 and 26 are therefore novel over each of these references. Claims 27 and 28 are therefore also novel by virtue of their dependency on claims 25 and 26.

The applicant contends that claims 29 is novel over the Masuda patents and the Heseltine patent for the same reasons as those given above.

The Waggoner 1981 reference does not disclose all of the features of claim 29 because it does not disclose components that contain at least one amino or hydroxyl group that is labelled with a luminescent dye. Furthermore, the Waggoner article does not mention the luminescence properties of labelled cattle rhodopsin; only the absorbance of the dye at 660 nm.

In item 13 of the Action the examiner has alleged that claims 25 to 29 are obvious over Masuda '289 when combined with Heseltine.

The examiner states (page 7 of the Action) that Heseltine teaches sulphonated cyanine and merocyanine dyes that are useful in photography. However, Heseltine does not teach cyanine dyes that are useful in labelling biological compounds for the reasons explained above.

The examiner also states (page 8 of the Action) that Masuda '289 teaches methods for labelling trace components such as antigens and antibodies. However, Masuda '289 does not teach luminescent dyes and luminescently labelled components that are detectable by luminescence detection methods.

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The examiner alleges that it would be obvious to one skilled in the art to use the water soluble dyes taught by Heseltine in the labelling method taught by Masuda '289. Both of these references refer to the dyes as being valuable and useful for use in photography as spectral sensitizers for silver halide emulsions. However, neither document refers to the luminescence properties of the compounds and neither document is concerned with dye-labelled components for luminescence detection.

The applicant respectfully contends that the skilled person would lack the necessary motivation to utilize the teachings of Masuda '289 either alone or when combined with Heseltine. It is stated in Masuda that an object of its invention is to provide a high sensitivity detection method and to measure multiple test samples using the same quantity of testing sample as used in the prior art. That object is realized according to Masuda by using a specific hydrazine compound, in conjunction with a conventional photographic measurement method, namely by using a dye to sensitize silver halide for detection.

Thus the detection modality is the same in the conventional process (from U.S. patent no. 4,337,063, cited in Masuda '289) as in the method described in Masuda '289. There is certainly no mention or suggestion of luminescence detection emitted by the labelling reagent. Neither is there any mention or suggestion of an alternative detection method over and above the silver halide detection method disclosed in Masuda '289. Furthermore, there is nothing in either Masuda or Heseltine that would motivate the skilled person to combine the documents in order to attempt direct luminescence detection.

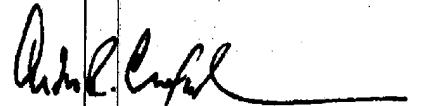
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For the above reasons it is respectfully submitted that claims 25-29 define inventive subject matter. Reconsideration and allowance are solicited.

Respectfully submitted,

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